# MAUDE Adverse Event Report: BAYER HEALTHCARE LLC ESSURE DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE



## BAYER HEALTHCARE LLC ESSURE DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE

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**Model Number** ESS305
**Event Date** 01/01/2014
**Event Type** Injury
**Event Description**

This is a spontaneous case report received from a gynecologist/obstetrician in (b)(6) on (b)(4) 2014. It describes the occurrence of pregnancy and device ineffective in a female patient of unspecified age who had essure (fallopian tube occlusion insert) inserted 2 years prior to this report. Follow-up information received on 13-jan-2015. No further information obtained despite follow-up attempts. Case closed. Follow-up received on 14-jan-2015: the patient was(b)(6) at the time of her event. Her weight was reported as (b)(6) and her height as (b)(6). Her drug history was positive for the use of micro-progestogen implant since (b)(6) 2009 (she experienced amenorrhea on this drug). She had essure model ess305 (lot number 915879) inserted on (b)(6) 2012; no uterine abnormalities were observed prior procedure. The hsg (hysterosalpingogram) performed on (b)(6) 2012 confirmed tubal occlusion and, because of that she discontinued her micro-progestogen implant on (b)(6) 2012. Her pregnancy was medically confirmed and the implants were found to be in place at the time of the diagnosis; she desired to interrupt the pregnancy. It was reported that the implants were removed (removal method: laparoscopy and hysteroscopy). The outer coil of the left device was broken by gynecologist and removed to allow the procedure of interruption of pregnancy (aspiration). The rest of the device (inner coil) was removed later by hysteroscopy on (b)(6) 2014. It was mentioned that the right implant was not seen during laparoscopy, but it was found during a post-surgery plain abdomen (discrepant with previous information about device removal). No pathological results, signs of infection or inflammation were observed. According to the physician, the removal of the implants was not medically necessary and was not performed due to patient's demand. Case upgraded to incident. Company causality comment: this medically confirmed spontaneous case report refers to a (b)(6) female patient who became pregnant 2 years after essure (fallopian tube occlusion insert) insertion. She decided to terminate the pregnancy; during this procedure the outer coil of the left device was broken by gynecologist and removed, the rest of left device was removed later by hysteroscopy. A laparoscopy was also performed and right implant was not found, but it was seen during post-surgery plain abdomen x-ray. The reported pregnancy was considered non-serious and is listed in essure's reference safety information. This event was considered as related to the suspect insert since patient had essure confirmatory test, which showed tubal occlusion. Therefore, an essure contraceptive failure cannot be excluded. Regarding the remaining events, interpreted as a device misuse followed by device breakage on left side and device dislocation on right side, they were considered as serious (except for device misuse) due to medical importance and are listed. Once essure is placed, micro-insert removal should not be attempted hysteroscopically unless 18 or more coils of the micro-insert are trailing. Also, the removal should be attempted immediately following the placement. If it is attempted, the micro-insert may break. For this particular case, considering the above mention information, the reported device breakage could be considered rather a consequence of device misuse; nevertheless given this event's nature a causal relationship with the suspect insert cannot be excluded. For the reported device dislocation as it was confirmed by laparoscopy and x-ray it was regarded as related to essure. This case was considered as incident, as although physician stated removal of the implants was not medically necessary, interventions were required. A product technical analysis is being sought.

**Manufacturer Narrative**

Ptc investigation result was received on 06-mar-2015. This adverse event report is related to a product technical complaint (ptc). The bayer reference number for the ptc report is: ptc global number (b)(4). Final assessment: batch number 915879 mfg date: 04/2013 exp date: 04/2016. Since no product was returned to us for investigation, we were unable to perform an investigation of the actual device involved in this complaint. Typically, we would inspect the micro-insert to look for any manufacturing deficiencies. In this case, we conducted a review of the manufacturing batch record and confirmed that final product testing for this lot was performed per requirements and the product met all release requirements. We are unable to confirm any quality defect or device malfunction at this

time. No new failure mode has been identified. Medical assessment: this ptc was initiated due to a lack of efficacy. A contraceptive failure may occur under the use of any contraceptive and is not indicative of a quality defect per se. No further ae case reports have been received to date with the referred batch. No batch signal could be identified. In this particular case, also a device breakage by the gynecologist was reported and considering the referred information, the reported device breakage could be considered rather a consequence of device misuse. The batch documentation of the reported batch was reviewed. No complaint sample was provided for a technical investigation at this point in time. The technical assessment concluded unconfirmed quality defect. The reported adverse event is a known possible undesirable event and not indicative of a quality deficit per se. In summary, there is no reason to suspect a causal relationship to a potential quality deficit based on this report. The list of similar cases contains reports with similar events coded in meddra. It includes recent cases received by bayer pharma and older cases received from the previous owner of the essure product (conceptus). These legacy reports have been re-coded according to bayer pharma standards. In this particular case a search in the database was performed on 10-mar-2015 for the following meddra preferred terms: device dislocation: the analysis in the global safety database revealed (b)(4) cases. Device breakage: the analysis in the global safety database revealed (b)(4) cases. Pregnancy with contraceptive device: the analysis in the global safety database revealed 2028. Bayer is closely monitoring the benefit-risk profile of essure. This includes consideration of the legacy cases in safety analyses. The cumulative review of the reports has not yielded any new safety signal. Company causality comment: this medically confirmed spontaneous case report refers to a (b)(6) female patient who became pregnant 2 years after essure (fallopian tube occlusion insert) insertion. She decided to terminate the pregnancy; during this procedure the outer coil of the left device was broken by gynecologist and removed, the rest of left device was removed later by hysteroscopy. A laparoscopy was also performed and right implant was not found, but it was seen during post-surgery plain abdomen x-ray. The reported pregnancy was considered non-serious and is listed in essure's reference safety information. This event was considered as related to the suspect insert since patient had essure confirmatory test, which showed tubal occlusion. Therefore, an essure contraceptive failure cannot be excluded. Regarding the remaining events, interpreted as a device misuse followed by device breakage on left side and device dislocation on right side, they were considered as serious (except for device misuse) due to medical importance and are listed. Once essure is placed, micro-insert removal should not be attempted hysteroscopically unless 18 or more coils of the micro-insert are trailing. Also, the removal should be attempted immediately following the placement. If it is attempted, the micro-insert may break. For this particular case, considering the above mention information, the reported device breakage could be considered rather a consequence of device misuse; nevertheless given this event's nature a causal relationship with the suspect insert cannot be excluded. For the reported device dislocation as it was confirmed by laparoscopy and x-ray it was regarded as related to essure. This case was considered as incident, as although physician stated removal of the implants was not medically necessary, interventions were required. The product technical analysis concluded unconfirmed quality defect. There is no reason to suspect a causal relationship to a potential quality deficit.

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**Type of Device** DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
**Manufacturer *(Section D)*** BAYER HEALTHCARE LLC
Milpitas CA
**Manufacturer *(Section G)*** BAYER HEALTHCARE LLC
1011 Mccarthy Blvd.
Milpitas CA 95035
**Manufacturer Contact** K. Shaw Lamberson
100 Bayer Blvd., P.o. Box 915
Whippany , NJ 07981-0915
**MDR Report Key** 4510083
**Report Number** 2951250-2015-00075
**Device Sequence Number** 1
**Product Code** KNH[24]
**Report Source** Manufacturer
**Source Type** Other,Foreign,Health Professional
**Reporter Occupation** Physician
**Type of Report** Initial,Followup
**Report Date** 03/26/2015
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**

**Date FDA Received** 02/12/2015
**Is This An Adverse Event Report?** Yes
**Is This A Product Problem Report?** Yes
**Device Operator** Health Professional
**Device EXPIRATION Date** 04/01/2016
**Device MODEL Number** ESS305
**Device LOT Number** 915879
**Was Device Available For Evaluation?** No
**Is The Reporter A Health Professional?** Yes
**Date Manufacturer Received** 03/06/2015
**Was Device Evaluated By Manufacturer?** Device Not Returned To Manufacturer
**Date Device Manufactured** 04/01/2013
**Is The Device Single Use?** Yes
**Type of Device Usage** Initial

**Patient TREATMENT DATA**
**Date Received: 02/12/2015 Patient Sequence Number: 1**

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Page Last Updated: 03/31/2016

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